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memorandum

DATE: January 31, 2001

REPLY TO ATTN OF: Office of Worker Protection Policy and Programs:Peter O'Connell:301-903-5641

SUBJECT: TECHNICAL POSITION REGARDING ACCEPTABLE APPROACHES TO IMPLEMENTING BIOASSAY PROGRAM REQUIREMENTS

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Since May 1995, my office has provided several clarifications and technical positions regarding the Department of Energy's (DOE) expectations concerning implementing selected provisions of Title 10 of the Code of Federal Regulations, Part 835 (10 CFR 835), "Occupational Radiation Protection." To assist field implementation of 10 CFR 835, we have developed, and are now distributing, the following Radiological Control Technical Position paper:

o "Questions and Answers Concerning Acceptable Approaches to Implementing Bioassay Program Requirements."

The attached technical position does not represent new policy or direction to the field. Rather, it provides clarification at the request of the field, Headquarters, and program offices to facilitate and promote the efficient and cost effective implementation of 10 CFR 835.

Please ensure further distribution of the attached documents to the applicable radiation protection organizations at your facilities. The DOE Radiological Control Coordinating Committee has reviewed these technical positions.

For additional information, please contact Mr. Peter O'Connell (Office of Worker Protection Policy and Programs) on 301-903-5641.

Steven V. Cary
Acting Assistant Secretary
Office of Environment, Safety and Health

Attachment

cc w/attachment:
See attached list

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Questions and Answers Concerning Acceptable Approaches to Implementing Bioassay Program Requirements

Issue:

The Department of Energy (DOE) Office of Safety and Health operates the Occupational Safety and Health (OSH) Response Line. Recently, several questions were submitted relating to requirements for implementation of internal dose monitoring programs required by Title 10 of the Code of Federal Regulations, Part 835 (10 CFR 835), *Occupational Radiation Protection.* Given the wide application of the issues, this Radiological Control Technical Position (RCTP) was written to disseminate this information to the DOE complex. In addition, DOE-STD-1121-98, *Internal Dosimetry,* is currently being revised and guidance from this RCTP will be included in the revision.

Discussion:

10 CFR 835 specifies requirements for internal dosimetry programs (including routine bioassay programs) for individuals based on the likelihood of their receiving an internal dose above a specified threshold. Guidance is provided on DOE's expectations for meeting these requirements.

Applicable Requirements

10 CFR 835 Occupational Radiation Protection

10 CFR 835.209 Concentrations of radioactive material in air.

(b) The estimation of internal dose shall be based on bioassay data rather than air concentration values unless bioassay data are:
  (1) unavailable;
  (2) inadequate; or
  (3) internal dose estimates based on air concentration values are demonstrated to be as or more accurate

10 CFR 835.402 Individual monitoring.

(c) For the purpose of monitoring individual exposures to internal radiation, internal dosimetry programs (including routine bioassay programs) shall be conducted for:

  (1) Radiological workers who, under typical conditions, are likely to receive a committed effective dose equivalent of 0.1 rem (0.001 sievert) or more from all occupational radionuclide intakes in a year;

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(d) Internal dose monitoring programs implemented to demonstrate compliance with § 835.402(c) shall be adequate to demonstrate compliance with the dose limits established in subpart C of this part.

Questions and Answers:

The following questions and answers provide the Office of Environment, Safety and Health techical positions on each topic.

Is internal dose monitoring required (either routine or ending-task) for all radionuclides that may contribute to a "likely" exposure of 100 mrem committed effective dose equivalent (CEDE) over the course of a year regardless of the magnitude of the contribution? If not, at what level may bioassay be considered not required?

For the purpose of compliance with 10 CFR 835.402(c)(1), all sources of occupational intakes must be included in making the determination that an individual is likely to receive a committed effective dose equivalent (CEDE) of 100 millirem or more in a year. For example, if a determination is made that an individual was likely to receive a CEDE of 95 millirem in a year from one radionuclide and this individual was also likely to receive a CEDE of 10 millirem in a year from another radionuclide, then that individual would need to be monitored in accordance with 10 CFR 835.402(c)(1).

After the determination is made that an individual needs to be included in the internal dosimetry program, the organization responsible for compliance with 10 CFR 835 must assess the anticipated magnitude of the occupational intakes from radionuclides to which the individual will be exposed and the feasibility and cost associated with monitoring at the anticipated exposure levels. At a minimum, the internal dosimetry program should include evaluation of dose from all radionuclides contributing significantly to the individual's dose.

The basis for including or excluding certain exposures to radionuclides in internal dosimetry programs should be documented in the site's Internal Dosimetry Technical Basis Document.

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Once an individual is identified as being "likely" to exceed 100 mrem CEDE over the course of a year either by being placed on a routine bioassay or by being assigned intakes that exceed 100 mrem CEDE in the year, is that individual required to continue on that program for the remainder of the year even though they no longer work in an area that exhibits the potential for 100 mrem CEDE exposure?

Generally, it is acceptable for the internal dosimetry program for an individual to be discontinued if that individual's work conditions have changed such that they are not likely, under typical conditions, to receive a CEDE of 100 millirem or more during the remainder of the year. However, per § 835.402(d), internal dose monitoring programs implemented to demonstrate compliance with § 835.402(c) need to be adequate to demonstrate compliance with the dose limits. Individuals who have already been assessed a dose approaching the dose limits may need to have continued monitoring to meet this requirement.

The decision for continued participation in the internal dosimetry program will require consideration of the individual's current dose, the anticipated dose for the remainder of the year, and types of radionuclides. If an individual will likely receive no additional dose for the rest of the year, or if additional internal dose will likely still result in a total internal dose of less than 100 millirem in a year, continued internal dose monitoring is not required. Other situations should be assessed on a case by case basis. Chapter 5 of DOE-STD-1121-98, *Internal Dosimetry*, gives examples of criteria for participation in a bioassay program, including guidance on ending-task bioassay participation and participation in routine bioassay programs if respiratory protection is used to limit intakes of radioactivity.

The basis for continuing or terminating individual participation in internal dosimetry programs should be documented in the site's Internal Dosimetry Technical Basis Document.

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Is a dose of record required to be assigned from derived air concentration (DAC)-hour tracking for those radionuclides where the missed dose from bioassay monitoring is greater than 100 mrem CEDE?

Depending on the reason for DAC-hour tracking, dose of record may not be required to be assigned from DAC-hour tracking, even for those radionuclides where the missed dose (from bioassay) is greater than 100 millirem CEDE. Per 10 CFR 835.402(d), the internal dose monitoring program needs to be able to demonstrate compliance with the dose limits. Accordingly, if use of available bioassay cannot demonstrate compliance with the dose limits or the purpose of the DAC-hour tracking is to assess the dose (per 10 CFR 835.209(b)), then DAC-hour tracking results would be used for the dose of record.

In addition, there are routine situations where there is a technology shortfall (i.e., section 4.1 of DOE-STD-1121-98, *Internal Dosimetry*, discusses technology shortfall as routine bioassay not capable of detecting doses of 100 millirem). In many of these situations, workplace indicators, such as tracking of exposures to derived air concentrations (DAC-hour), do not trigger special bioassay evaluation yet they indicate that internal doses of 100 millirem or greater in a year are likely. For these situations, it is highly recommended that use of air concentration data, which are representative of the air the worker breathed, be used for assessing internal dose. This approach is preferable to use of bioassay results which indicate no detectable activity. For example, air concentration values indicating a 40 DAC-hour exposure (100 millirem) should be considered for assessing internal dose if subsequent negative bioassay results are obtained based on an analytical process that is only capable of detecting exposures in excess of 100 millirem. This is consistent with guidance found in DOE-STD-1121-98, *Internal Dosimetry*, sections 4.4.5, 6.1 and 7.7.

Initiating timely special bioassay (e.g., fecal bioassay shortly after working in a plutonium environment with a respirator or in response to elevated workplace monitoring results) may be helpful in the detection of internal exposures with bioassay. A timely special bioassay may provide a better basis for determining internal exposures than DAC-hour tracking results.

The basis for either assessing dose from DAC-hour tracking, or not, when there is a bioassay program technology shortfall should be documented in the site's Internal Dosimetry Technical Basis Document.

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What are the required parameters for calculating the sensitivity of the internal dosimetry program (i.e., missed dose)? For example:
a) Intake Date - maximum, midpoint, etc?
b) Solubility - most conservative, mixtures, or other?
c) Is the minimum detectable activity (MDA) or decision level (DL) used as the determination for predicted positive bioassay sample?
d) Particle Size - 1 micron, site default or other?
e) Lung Model?

In general, lacking contrary physical evidence, reasonably conservative assumptions should be used in conjunction with appropriate biokinetic models and the analytical MDA in determining the sensitivity of the internal dosimetry program. DOE-STD-1121-98, *Internal Dosimetry*, provides guidance on many of these topics, including section 7.4.1.3, which discusses assumptions on time of intake. The site specific parameters and their basis should be documented in the site's Internal Dosimetry Technical Basis Document.

Summary:

All radionuclides contributing to occupational exposure need to be considered when deciding if an individual is likely to receive a committed effective dose equivalent of 100 millirem or more from all occupational radionuclide intakes in a year.

An assessment of which radionuclides to include in internal dose monitoring programs should be conducted. At a minimum, the internal dosimetry program should include evaluation of dose from all radionuclides contributing significantly to the individual's dose.

If work conditions change such that an individual will likely receive no additional dose for the rest of the year or that additional dose will likely still result in a total dose of less than 100 millirem in a year, continued internal dose monitoring is not required. Other situations should be assessed on a case by case basis.

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For situations involving bioassay program technology shortfalls where exposures exceeding 100 millirem are likely, one should assess dose based on DAC-hour tracking.

Use models appropriate to the site exposure scenarios or use reasonably conservative assumptions and MDA (not DL) of the bioassay analysis when determining the sensitivity of the internal dosimetry program (i.e., missed dose).

The basis for site implementation of the internal dosimetry program should be documented in the site's Internal Dosimetry Technical Basis Document.

References:

10 CFR 835, *Occupational Radiation Protection*, U.S. Department of Energy, November 4, 1998

DOE-STD-1121-98, *Internal Dosimetry*, U.S. Department of Energy, December 1999